

follow-up to the Notice of Appeal submitted February 29, 1996.

Applicants hereby request that the "finality" of the rejection be withdrawn under 37 C.F.R. § 1.129(a) and that this First Submission after Final Rejection be entered and considered on the merits. The Assistant Commissioner is hereby authorized to charge the \$750.00 fee required under 37 C.F.R. § 1.17(r) to Deposit Account No. 23-1703.

PETITION FOR EXTENSION OF TIME

Applicants hereby request a four-month extension of time extending the time for response following the filing from the Notice of Appeal from April 29, 1996 up to and including August 29, 1996. The Assistant Commissioner is hereby authorized to charge the required \$1,400.00 extension fee to Deposit Account No. 23-1703. Any additional fees due in connection with this petition should likewise be charged.

Please amend the application as follows:

In the claims:

1. (four times amended) A medicament containing as active ingredients effective amounts of a physiologically acceptable salt of formoterol or a solvate thereof, and budesonide wherein the molar ratio of the formoterol

component to the budesonide component is in the range from 1:4 to 1:60.

2. (thrice amended) A pharmaceutical composition which comprises effective amounts of a physiologically acceptable salt of formoterol or a solvate thereof, and budesonide wherein the molar ratio of the formoterol component to the budesonide component is in the range from 1:4 to 1:60, together with a pharmaceutically acceptable carrier.

17. (thrice amended) A method for the treatment of asthma and other inflammatory respiratory disorders which comprises administering by inhalation to a host in need of such treatment effective amounts of a physiologically acceptable salt of formoterol or a solvate thereof, and budesonide wherein the molar ratio of the formoterol component to the budesonide component is in the range from 1:4 to 1:60.

Sub 3' 17. (amended) [The] A method [according to claim 7] for the treatment of asthma and other inflammatory respiratory disorders, which comprises administering by inhalation to a host in need of such treatment effective amounts of a physiologically acceptable salt of formoterol or a solvate thereof, and budesonide, wherein the effective amount of the physiologically acceptable salt of formoterol

E3 or solvate thereof is 6-100 μ g per day, and the effective amount of budesonide is 50-4800 μ g per day.

E4 20. (amended) The method according to any one of claims ¹⁷ [and 17-19], ¹⁸ ¹⁹ and ¹⁸ wherein the administration is performed from a dry powder inhaler.

22. (amended) The method according to any one of claims ¹⁷ [and 17-19], ¹⁸ ¹⁹ and ¹⁸ wherein the administration is performed from a metered dose inhaler.

E5 23. (amended) The method according to any one of claims ¹⁷ [and 17-19], ¹⁸ ¹⁹ and ¹⁸ wherein the formoterol is in the form of the fumarate dihydrate.

E Please cancel claim 19.

Please add the following new claims:

E ~~24~~. A pharmaceutical composition according to claim ⁴ wherein the pharmaceutically acceptable carrier is lactose.

E ⁷ ~~25~~. A pharmaceutical composition according to claim ⁶ ~~24~~ in dosage unit form.

E6 ⁸ ~~26~~. A pharmaceutical composition according to claim ⁷ ~~25~~ comprising 12 μ g formoterol fumarate dihydrate, 200 μ g budesonide and up to 25 mg lactose.

²⁴ ~~27~~. The method according to any one of claims ¹⁷ ¹⁸ ¹⁹ ~~7~~, ~~17~~ and ~~18~~ wherein the administration is performed with a nebulizer.